In the Claims

Claims 1-58 (Canceled)

59. (Currently amended) A polymer film for topical transmucosal delivery of therapeutic agents ~~comprising~~ prepared from an evaporated solution consisting essentially of a therapeutic agent, a substrate polymer, a penetration enhancer, a surfactant and plasticizer,

wherein said substrate polymer is selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, a copolymer of polyoxypropylene-polyoxyethylene (poloxamer), carboxypolymethylene (carbopol), polycarbophil, polycarbophil acid, polycarbophil acid crosslinked by di-vinyl glycol, alginic acid, alginic acid sodium salt, polyacrylic acid crosslinked by di-vinyl glycol, polyacrylic acid, polypropylene glycol, polypropylene glycol alginate, polypropylene oxide, carboxymethyl cellulose, polylactide, polyglycolide, polyvinyl ether and poly-1-vinyl-2-pyrrolidinone, each alone or in admixture, present in from about 2% to about 100%, by weight;

wherein said therapeutic [[~~a~~]] agent is selected from the group consisting of non-steroidal anti-inflammatory agent, calcium channel antagonist agent, local anesthetic agent, vasodilatory agent, cyclooxygenase (COX) inhibitor agent, anti-migraine agent, anti-nausea agent, anti-osteoporotic agent and a biotechnology derived protein or peptide, each alone or in admixture, present in amount from about 0.1 to about 2000 mg;

wherein said penetration enhancer is selected from the group consisting of sodium caproate, sodium caprylate, sodium caprate, sodium laurate, sodium myristate, sodium palmitate, sodium palmitoleate, sodium oleate, sodium ricinoleate, sodium linoleate, sodium stearate, sodium lauryl sulfate, sodium tetradecyl sulfate, sodium lauryl

sarcosine, sodium dioctyl sulfosuccinate, disodium polyoxyethylene-10 oleyl ether phosphate, esterification product of fatty alcohols, citric acid, citric acid esters of mono- and diglycerides, ethoxylated alkyl sulfate, octyl sulfosuccinate disodium, phosphatidyl glycerol, glycyrrhetinic acid, acylcarnitine, chitosan, palmitoyl-D,L-carnitine, polyoxyethylene monooleyl ether, ethoxydiglycol, 2-hydroxypropyl-β-cyclodextrin, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glyceride, polyoxyethylene vegetable or hydrogenated oil, polyoxyethylene hydrogenated castor oil, polyoxyethylene almond oil, polyoxyethylene apricot kernel oil, glyceride, polyoxyethylene caprylic glyceride, polyoxyethylene capric glyceride and lauroyl macrogol glyceride, present in from about 0.1% to about 60%, by weight;

wherein said plasticizer is selected from the group consisting of glycerin, polyethylene glycol, propylene glycol, sorbitol and triacetin, present in from about 5% to about 25%, by weight;

wherein said surfactant is selected from the group consisting of polysorbate (Tween 80), sodium lauryl sulfate and a non-ionic surfactant (Brij), present in from 0.01% to about 5%, by weight;

wherein said film is prepared as a single or double sided solid or semi-solid film strip, film pad, film pillow, film tube, film sheet, film sphere, film ring, film sheet, or as a liquid preparation that forms a film layer upon contact with an epithelial tissue or with a surface of non-film device made of different material, and

wherein at least 55% of said therapeutic agent is released from said film within two hours

~~said polymer film suitable for topical delivery of a therapeutically effective agent~~ onto a vaginal, nasal, buccal, scrotal or labial epithelium and delivered through said epithelium into systemic circulation.

60. (Previously presented) The polymer film of claim 59 wherein said therapeutic agent is the non-steroidal anti-inflammatory agent selected from the group consisting of ketorolac, aspirin, ibuprofen, indomethacin, phenylbutazone, bromfenac, fenamate, sulindac, nabumetone and naproxen, the anti-osteoporotic agent selected from the group consisting of alendronate, clodronate, etidronate, pamidronate, tiludronate, ibandronate, alpadronate, residronate, neridronate and zoledronic acid, the anti-nausea agent selected from the group consisting of aprepitant, cyclizine, dolasetron, domperidone, dronabinol, levonantradol, metoclopramide, nabilone, ondansetron, prochlorperazine, promethazine and tropisetron, and the biotechnology derived protein or peptide selected from the group consisting of insulin, calcitonin, somatostatin, vasopressin, luprolide, oxytocin, bivalirudin, integrilin, natrecor, abarelix, gastrine G17 peptide, ziconotide, cereport, interleukins, humanized antibodies and growth hormone.

61. (Previously presented) The polymer film of claim 60 wherein said substrate polymer is hydroxypropyl methyl cellulose, polypropylene glycol, microcrystalline cellulose, polyethylene oxide, alginic acid or a mixture thereof, present in from about 70% to about 97%, by weight.

62. (Previously presented) The polymer film of claim 60 wherein said penetration enhancer is phosphatidyl glycerol, ethoxydiglycol, polyoxyethylene glyceride fatty acid ester, polyoxyethylene caprylic glyceride, lauroyl macrogol glyceride, chitosan, acylcarnitine or palmitoyl-D,L-carnitine, present in from about 60%, by weight.

63. (Previously presented) The polymer film of claim 60 wherein said surfactant is Tween 80, present in about 3%, by weight.

64. (Previously presented) The polymer film of claim 60 wherein said plasticizer is glycerol, polyethylene glycol, propylene glycol, sorbitol or triacetin, present in from about 5% to about 15%, by weight.

65. (Previously presented) The polymer film of claim 60 further comprising a buffer selected from the group consisting of potassium metaphosphate, potassium phosphate, disodium phosphate, monobasic sodium acetate, sodium carbonate, sodium bicarbonate, tartaric acid, citric acid, tris citrate and triethanolamine, present in from about 1% to about 50%, by weight.

66. (Previously presented) The polymer film of claim 60 wherein said therapeutic agent is anti-inflammatory agent released from said polymeric film at a release rate of 50% within 80 minutes.

67. (Previously presented) The polymer film of claim 66 comprising about 74.3%, by weight, polyethylene oxide and hydroxypropyl methylcellulose substrate polymer admixture, about 16%, by weight, of Tween 80 solubilizer and sorbitol plasticizer, about 0.1%, by weight, of anti-inflammatory agent ketorolac, and additionally comprising 0.5%, by weight, a mixture of an antioxidant butylated hydroxyanisol (BHA) and butylated hydroxytoluene (BHT).

68. (Previously presented) The polymer film of claim 67 wherein said anti-inflammatory agent is ketorolac released from said film at

a release rate from about 2% to about 3.8%/minute.

69. (Currently amended) The polymer film of claim 66 comprising, in an admixture, about 14.9%, by weight polyethylene oxide[[,]] and about 59.4% of hydroxypropyl methylcellulose, about 15.6%, by weight, of Tween 80, about 0.5% of sorbitol, about 9.1%, by weight, of ketorolac tromethamine, and additionally comprising 0.4%, by weight, of butylated hydroxyanisol (BHA) and 0.2% of butylated hydroxytoluene (BHT).

70. (Withdrawn) The polymer film of claim 60 wherein said therapeutic agent is an anti-osteoporotic agent alendronate released from said film at a release rate from about 3.9% to about 7.3%/minute.

71. (Withdrawn) The polymer film of claim 60 wherein said therapeutic agent is a biotechnology derived protein or peptide.

72. (Withdrawn) The polymer film of claim 71 wherein said protein is calcitonin released from said film at a release rate in about 0.2%/minute.

73. (Currently amended) The polymer film of claim 60 comprising about 47.3%, by weight, polyethylene oxide and propylene glycol alginate substrate polymer admixture, about 49.6%, by weight, of citric acid and sodium citrate as a buffer mixture, about 2.5%, by weight, a mixture of Tween 80 solubilizer and sorbitol plasticizer, and additionally comprising about 0.6%, by weight, of an antioxidant butylated hydroxyanisole (BHA) ~~α-tocopherol polyethylene glycol succinate~~.

74. (Currently amended) The polymer film of claim 60 comprising about 42.3%, by weight, of polyethylene oxide, 5%, by weight, of propylene glycol alginate, about 24.8%, by weight, of citric acid, about 24.8, by weight, of sodium citrate, about 2%, by weight, of Tween 80, about 0.5%, by weight, sorbitol plasticizer, and additionally comprising about 0.7%, by weight, of antioxidant butylated hydroxyanisole (BHA) ~~α-tocopherol polyethylene glycol succinate~~.

75. (Previously presented) The polymer film of claim 60 prepared as from 0.5 mm to about 2 mm layer.

76. (Previously presented) The polymeric film of claim 60 wherein said device made of different material is a conventional tampon, pessary, ring, strip, pad, pillow, sheet, tube, sphere, tablet or bead.

77. (Withdrawn) A polymeric foam device for topical delivery of a therapeutic effective agent to a vaginal, nasal, buccal, scrotal or labial epithelium and through said epithelium into systemic circulation, said device comprising a substrate polymer, and a therapeutic agent, and additionally comprises a penetration enhancer, a solubilizer, a plasticizer and a buffer,

wherein said substrate polymer is selected from the group consisting of polyethylene oxide, hydroxypropyl methylcellulose, poloxamer, carbopol, polycarbophil, polycarbophil acid, polycarbophil acid crosslinked by di-vinyl glycol, alginic acid, alginic acid sodium salt, polyacrylic acid crosslinked by di-vinyl glycol, polyacrylic acid, polypropylene glycol, polypropylene glycol alginate, polypropylene oxide, carboxymethyl cellulose, polylactide, polyglycolide, polyvinyl ether, and poly-1-vinyl-2-pyrrolidinone, each

alone or in admixture, present in from about 5% to about 100%, by weight;

wherein said therapeutical agent is selected from the group consisting of non-steroidal anti-inflammatory agent, calcium channel antagonist agent, local anesthetic agent, vasodilatory agent, cyclooxygenase (COX) inhibitor agent, antifungal agent, anti-migraine agent, anti-osteoporotic agent and a biotechnology derived protein or peptide, each alone or in admixture, present in amount from about 0.1 to about 2000 mg;

wherein said penetration enhancer is selected from the group consisting of sodium caproate, sodium caprylate, sodium caprate, sodium laurate, sodium myristate, sodium palmitate, sodium palmitoleate, sodium oleate, sodium ricinoleate, sodium linoleate, sodium stearate, sodium lauryl sulfate, sodium tetradecyl sulfate, sodium lauryl sarcosine, sodium dioctyl sulfosuccinate, disodium polyoxyethylene-10 oleyl ether phosphate, esterification product of fatty alcohols, citric acid, citric acid esters of mono- and diglycerides, ethoxylated alkyl sulfate, octyl sulfosuccinate disodium, phosphatidyl glycerol, glycyrrhetinic acid, acylcarnitine, palmitoyl-D,L-carnitine, polyoxyethylene monooleyl ether, ethoxydiglycol, 2-hydroxypropyl-β-cyclodextrin, polyoxyethylene glycerol fatty acid ester, polyoxyethylene glyceride, polyoxyethylene vegetable or hydrogenated oil, polyoxyethylene hydrogenated castor oil, polyoxyethylene almond oil, polyoxyethylene apricot kernel oil, glyceride, polyoxyethylene caprylic glyceride, polyoxyethylene capric glyceride and lauroyl macrogol glyceride present in from about 0.1% to about 60%, by weight;

wherein said plasticizer is selected from the group consisting of glycerin, water, polyethylene glycol, propylene glycol, sorbitol and triacetin, present in from about 5% to about 25%, by weight;

wherein said surfactant is selected from the group consisting of polysorbate (Tween 80), sodium lauryl sulfate and a non-ionic surfactant (Brij), present in from 0.01% to about 5%, by weight;

wherein said buffer is selected from the group consisting of potassium metaphosphate, potassium phosphate, disodium phosphate, monobasic sodium acetate, sodium carbonate, sodium bicarbonate, tartaric acid, citric acid, tris citrate and triethanolamine, present in from about 1% to about 57%, by weight;

wherein said foam device is preformed into a solid or semi-solid foam tampon, foam tablet, foam cylinder, foam strip, foam pad, foam pillow, foam tube, foam sheet, foam sphere, foam ring or foam bead, or is a liquid preparation that forms a foam layer device upon contact with an epithelial tissue or with a surface of non-foam device made of different material.

78. (Withdrawn) The polymer foam of claim 77 wherein said therapeutic agent is the non-steroidal anti-inflammatory agent selected from the group consisting of ketorolac, aspirin, ibuprofen, indomethacin, phenylbutazone, bromfenac, fenamate, sulindac, nabumetone and naproxen, the anti-osteoporotic agent selected from the group consisting of alendronate, clodronate, etidronate, pamidronate, tiludronate, ibandronate, alpadronate, residronate, neridronate and zoledronic acid, the antifungal agent selected from the group consisting of miconazole, terconazole, isoconazole, fenticonazole, tioconazole, fluconazole, nystatin, ketoconazole, clotrimazole, butoconazole, econazole, metronidazole and itraconazole, and the biotechnology derived protein or peptide selected from the group consisting of insulin, calcitonin, somatostatin, vasopressin,

luprolide, oxytocin, bivalirudin, integrilin, natrecor, abarelix, gastrine G17 peptide, ziconotide, cereport, interleukins, humanized antibodies and growth hormone.

79. (Withdrawn) The polymer foam of claim 78 wherein said substrate polymer is hydroxypropyl methyl cellulose, polypropylene glycol, microcrystalline cellulose, polyethylene oxide, alginic acid or a mixture thereof, present in from about 20% to about 60%, by weight.

80. (Withdrawn) The polymer foam of claim 78 wherein said penetration enhancer is phosphatidyl glycerol, ethoxydiglycol, polyoxyethylene glyceride fatty acid ester, polyoxyethylene caprylic glyceride, lauroyl macrogol glyceride, acylcarnitine or palmitoyl-D,L-carnitine, present in from about 10% to about 15%, by weight.

81. (Withdrawn) The polymer foam of claim 78 wherein said surfactant is Tween 80, present in from about 7.8 to about 70.9%, by weight.

82. (Withdrawn) The polymer foam of claim 78 wherein said plasticizer is glycerol, polyethylene glycol, propylene glycol, sorbitol or triacetin, present in about 20%, by weight.

83. (Withdrawn) The polymer foam of claim 78 wherein said therapeutic agent is anti-inflammatory agent released from said polymeric foam at a release rate of 50% within about 30 to about 120 minutes.

84. (Withdrawn) The polymer foam of claim 83 wherein said anti-inflammatory agent is ketorolac released from said film at a release rate from about 2% to about 3.8%/minute.

85. (Withdrawn) The polymeric foam device of claim 78 wherein said device releases the incorporated drug at a maximum release rate of about 50 to about 100%.

86. (Withdrawn) The device of claim 78 wherein said device is uptaking water at a rate of about 33 mg to about 226 mg of water/minute.